

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) Application Division
 Par GELLERSFORS) ATTN: PCT
 Serial No.: 10/048,234) Washington, D.C.
 IA Filing Date: July 27, 2002) Date: September 30, 2002
 For: PRODUCTION OF pHPGD AND NEW THERAPEUTIC METHODS FOR TREATING PATIENTS WITH
 ACUTE INTERMITTENT PORPHYRIA (AIP) AND OTHER POPYRIC DISEASES

LATE SUBMISSION OF DECLARATION AND/OR TRANSLATION IN APPLICATION FILED UNDER 35 USC
371

HON. COMMISSIONER OF PATENTS AND TRADEMARKS
 Washington, D.C. 20231

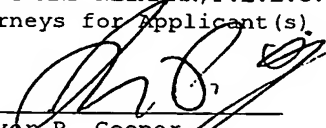
Sir:

The present communication is in response to the "NOTICE OF MISSING REQUIREMENTS UNDER 35 USC 371..." dated July 23, 2002.

- [XX] Attached hereto is an executed oath or declaration in compliance with 37 C.F.R. 1.63, identifying the present application by title, priority information, and PCT information.
- [] Applicant claims small entity status. See CR 1.27.
- [XX] Response to Notice to Comply with Sequence Listing Requirements and Statements in Support of Filing and Submissions in Accordance with 37 C.F.R. '1.821-1.825, Sequence Listing (hardcopy), and computer-readable form of Sequence Listing.
- [] An Information Disclosure Statement with 1449 and references is also attached.
- [] A Preliminary Amendment
- [] An exact English language translation of the PCT application as originally filed.
- [] Other documents: _____
- [] Surcharge for late filing of English translation \$ 130.00
- [XX] Surcharge for late filing of the Declaration was paid on January 28, 2002.
- [] Surcharge for late filing of the Declaration in the amount of:
- | | |
|--------------|-------------------------|
| Small Entity | Other than Small Entity |
| [] \$65.00 | [] \$130.00 |
- [] It is hereby petitioned for an extension of time in accordance with 37 C.F.R. 1.136(a). The appropriate fee required by 37 C.F.R. 1.17 is calculated as shown below:
- | | |
|------------------------|-------------------------|
| Small Entity | Other Than Small Entity |
| Response Filed Within | Response Filed Within |
| [] First - \$ 55.00 | [] First - \$ 110.00 |
| [] Second - \$ 200.00 | [] Second - \$ 400.00 |
| [] Third - \$ 460.00 | [] Third - \$ 920.00 |
| [] Fourth - \$ 720.00 | [] Fourth - \$1,440.00 |
| [] Fifth - \$ 980.00 | [] Fifth - \$1,960.00 |

- Month After Time Period Set Month After Time Period Set
- [XX] Conditional Petition for Extension of Time:
 If any extension of time for a response is required, applicant requests that this be considered a petition therefor.
- [XX] Credit Card Payment Form, PTO-2038, authorizing payment the amount of \$84.00 is enclosed to cover the above fees.
- [XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR 1.16 and all patent processing fees under 37 CFR 1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR 1.18.

BROWDY AND NEIMARK, P.L.L.C.
 Attorneys for Applicant(s)

By: 
 Ivar P. Cooper
 Registration No. 21,082



UNITED STATES PATENT AND TRADEMARK OFFICE

 Commissioner for Patents, Box PCT
 United States Patent and Trademark Office
 Washington, D.C. 20231
 www.uspto.gov

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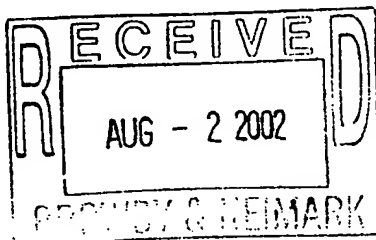
U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/048,234	Par Gellerfors	GELLERFORS2

INTERNATIONAL APPLICATION NO.

PCT/DK00/00425

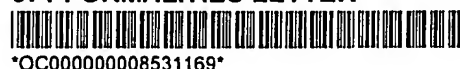
I.A. FILING DATE	PRIORITY DATE
07/27/2000	07/27/1999

Browdy and Neimark
 624 Ninth Street N W
 Suite 300
 Washington, DC 20001



CONFIRMATION NO. 4358

371 FORMALITIES LETTER



OC000000008531169

Date Mailed: 07/29/2002

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fees
- Priority Document
- Biochemical Sequence Listing
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- Preliminary Amendments
- Request for Immediate Examination

MSP/SEQ=
 29SE2002
 DKT 8.5.02

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTH FROM THE DATE OF THIS NOTICE OR BY 22 or 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Additionally the following defects have been observed:

The following items **MUST** be furnished within the period set forth below:

- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):

- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
- **APPLICANT MUST PROVIDE:**
 - An initial or substitute computer readable form (CRF) of the "Sequence Listing."
 - A statement that the contents of the paper or compact disc and the computer readable form are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).

- For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase Patent Software, call (703) 306-2600
- For Patent Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

- Additional claim fees of **\$84** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$84** for a Large Entity:

- Total additional claim fee(s) for this application is **\$84**
 - **\$84** for 4 independent claims over 3.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

KAREN R MCLEAN

Telephone: (703) 308-9117

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/048,234	PCT/DK00/00425	GELLERFORS2

#4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	ART UNIT:
)	
GELLERFORS et al.)	Examiner:
)	
Appln. No.: 10/048,234)	Washington, D.C.
)	
I.A. Filing Date: July 27, 2000)	September 30, 2002
)	
For: PRODUCTION OF pHPGD AND)	Atty.Docket: GELLERFORS=2
NEW THERAPEUTIC METHODS..)	
)	
Confirmation No.: 4358)	

RESPONSE TO "SEQUENCE LISTING" REQUIREMENT

Honorable Commissioner of Patents
Washington, D.C. 20231

Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US), mailed July 29, 2002, please amend the application as follows:

IN THE SEQUENCE LISTING

Please substitute the attached Sequence Listing, numbered as pages 1-11 for the Sequence Listing previously submitted.

REMARKS

1. Applicants hereby submit the following:
 - [] a paper copy of a "Sequence Listing", complying with §1.821(c), to be incorporated into the specification as directed above;
 - [] an amendment to the paper copy of the "Sequence Listing" submitted on July 27, 2000, the amendment being in the form of substitute sheets;
 - [XX] the Sequence Listing in computer readable form, complying with §1.821(e) and §1.824, including, if an amendment to the paper copy is submitted, all previously submitted data with the amendment incorporated therein;
 - [] a substitute computer readable form to replace one found to be damaged or unreadable.
 - [] The computer readable form in this application no. 09/... is identical with that filed on [date sequence was filed] in application no. 09/ , filed [filing date]. In accordance with 37 C.F.R. §1.821(e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the instant application. A paper

copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].

[XX] 2. The description is in compliance with §1.821(d).

3. The undersigned attorney or agent hereby states as follows:

- (a) this submission is not believed to include new matter [§1.821(g)];
- (b) the contents of the paper copy (as amended, if applicable) and the computer readable form of the Sequence Listing, are believed to be the same [§1.821(f) and §1.825(b)];
- (c) if the paper copy has been amended, the amendment is believed to be supported by the specification and is not believed to include new matter [§1.825(a)]; and
- (d) if the computer readable form submitted herewith is a substitute for a form found upon receipt by the PTO to be damaged or unreadable, that the substitute data is believed to be identical to that originally filed [§1.825(d)].

4. Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown"

origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

The Examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any


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further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By:


Iver P. Cooper
Registration No. 28,005

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